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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,817	01/07/2005	Henrik Lindenskov Nielsen	P70346US0	5100
136 7590 12/26/2007 JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			EXAMINER BOGART, MICHAEL G	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 12/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,817

Applicant(s)

NIELSEN ET AL.

Examiner

Michael G. Bogart

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,25-32 and 35-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,25-32 and 35-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Objections

Claims 35 and 40 are objected to because of the following informalities:

Claim 35 depends from canceled claim 24. Claim 40 appears to depend from both claims 23 and 24. For the purposes of examination against the prior art, claims 35 and 40 are considered to depend from claim 23. Appropriate correction is required.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

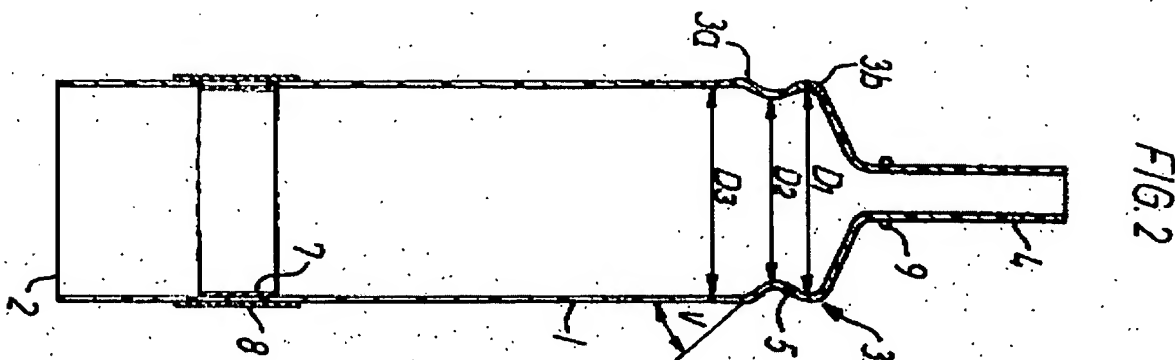
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 23, 25-27, 35, 39, 44, 45, 47 and 48 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wendler (US 5,554,141 A) in view of Oda (EP 1 062 957 A1; hereinafter: "Oda"), Endo *et al.* (US 5,417,981 A; hereinafter: "Endo"), Hull *et al.*, (US 4,710,532; hereinafter "Hull") and Lee *et al.* (US 6,520,934 B1, hereinafter: "Lee").

Regarding claims 23, 25 and 44, Wendler teaches an external urinary catheter (1) and method of making the same, comprising a tip portion (34) and a sheath portion (1), said external urinary catheter (1) having thermoplastic construction (abstract)(col. 5, lines 27-38).



Wendler is silent as to the catheter's specific plasticizer and copolymer materials.

Oda teaches a flexible, elastic and transparent medical device including a catheter comprising a composition of styrene-ethylene random copolymer and a plasticizer to which

further polymeric compounds can be added (paragraphs 0001, 0002, 0008, 0009 and 0065, and 0076).

Endo teaches catheters utilizing ethylene-polypropylene-diene terpolymer (col. 3, line 57- col. 4, line 4; claim 11).

Hull teaches catheters using citrate plasticizers (col. 1, lines 11-30).

Lee teaches catheters using polyamide-polyethylene block copolymer (col. 3, lines 45- 54).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to use the plasticizers and polymers of Oda, Hull, Lee and Endo in the catheter of Wendler in order to provide materials known in the art to be suitable for that purpose.

Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of

ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

Regarding claims 23 and 39, the specific ranges of concentrations of materials, optimization of ranges within prior art conditions or through routine experimentation is not sufficient to patentably distinguish an invention over the prior art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Regarding claim 26, Wendler teaches a slip additive comprising erucamide (col. 6, lines 35-46).

Regarding claims 27 and 48, optimization of ranges within prior art conditions or through routine experimentation is not sufficient to patentably distinguish an invention over the prior art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

One of ordinary skill in the art would have recognized the benefits of making the device as transparent as possible (see Oda, paragraph 0003) while managing competing factors such as cost, materials availability, etc.

Regarding claim 35, Oda teaches the addition of a polymer (paragraph 0063).

Regarding claim 45 and 47, Wendler teaches that subcomponents of the catheter can be made by extrusion and injection molding (col. 4, lines 1-25; col. 7, lines 52-61).

Claims 28-32, 36-38, 40-43, 46, 49 and 50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wendler, Oda, Endo, Hull and Lee as applied to claims 23, 25-27, 35, 39, 44, 45, 47 and 48 above, and further in view of Stehr *et al.* (WO 96/29962 A1; hereinafter "Stehr").

Regarding claim 46, Wendler in view of Oda, Endo, Hull and Lee do not disclose a tip manufactured separately from the sheath.

Stehr teaches a condom catheter where the sheath and tip are manufactured separately (page 5, line 20-page 6, line 13).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to separately form the tip and sheath as shown by Stehr in the device and methods of Wendler and Oda in order to provide for a catheter with a tip with different physical properties (for example, breathability) than the sheath.

Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that

only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

Regarding claims 28 and 32, Stehr teaches a breathable condom catheter (page 4, lines 13-17).

Regarding claims 29, 49 and 50, the references do not disclose the claimed ranges of values for thickness and permeability.

Optimization of ranges within prior art conditions or through routine experimentation is not sufficient to patentably distinguish an invention over the prior art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

One of ordinary skill in the art would have recognized the benefit of increasing the permeability as much as possible while keeping it liquid-tight. Thinner material lead to a more conformable product, while thicker materials have greater strength.

Regarding claims 30 and 31, Stehr teaches that the elastomer is a polyurethane (page 4, lines 13-17).

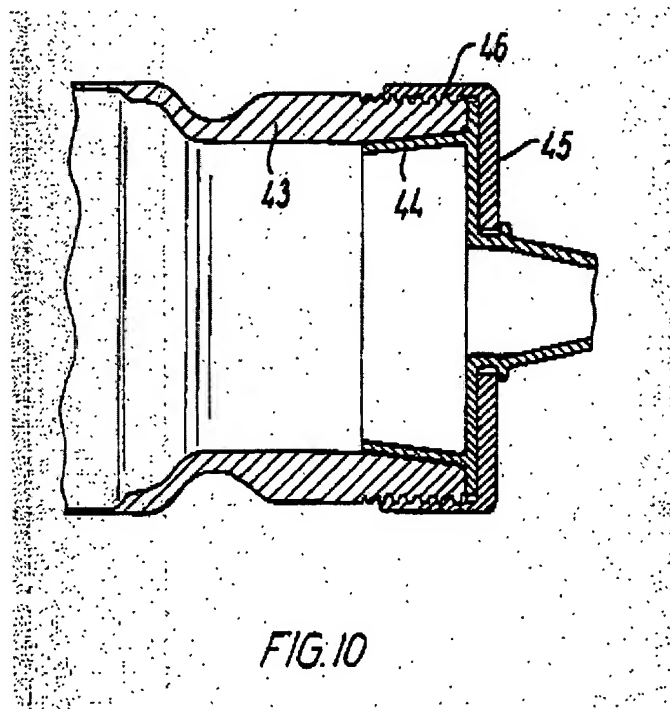
Regarding claims 36 and 37, Oda teaches the addition of a polymer (paragraph 0063).

Regarding claim 38, Oda teaches a polyethylene elastomer (paragraph 0058).

Regarding claims 40 and 41, Wendler teaches a pressure-sensing adhesive (7) and an adhesive rejecting/release layer (8).

Regarding claim 42, Wendler teaches a separate adhesive element (7).

Regarding claim 43, Wendler teaches interlocking elements (46)(see figure 10, infra).



Response to Arguments

The rejections under Conway are withdrawn.

Applicants assert that Wendler and Oda do not show the same % ranges of citrate plasticizer as the claimed invention. This argument is not persuasive, because as presently applied, the combination of references teaches all of the claimed materials of the instant invention. As far as the specific % ranges of those materials, it would have been obvious at the time of the invention for someone of ordinary skill in the art to optimize those values. See detailed discussion, *supra*.

Regarding applicants arguments concerning their was no incentive to combine the various elements from the multiple references to arrive at the claimed invention, see the detailed discussion of *KSR*, *supra*.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart
20 December 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

